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Re: Comments on Proposed Interim Final Rule for Possession, Use, and Transfer of Select Agents 42 CFR Part 73

January 13, 2003

To Whom It May Concern:

The following comments represent the views of Stanford University with regard to the Proposed Interim Final Rule for Possession, Use, and Transfer of Select Agents 42 CFR Part 73, issued in the Federal Register on December 13, 2002.

1. 42 CFR 73.10(c): " An entity may not conduct the following experiments unless approved by the HHS Secretary after consultation with experts:
   (1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
   (2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight."

Federally- funded scientists are already subject to the above restriction under National Institutes of Health (NIH) guidelines, which require the agency's Recombinant DNA Advisory Committee (RAC) to approve such experiments. This same regulation requires ALL experiments at an institution that receives NIH funding to comply with the rDNA guidelines as stated by the NIH, regardless of the source of funding for a particular experiment.

We suggest that HHS consolidate its oversight needs with those of NIH and use the already established NIH-RAC to review proposals as needed. Appropriate legislation could ensure that all research involving experiments described in 42 CFR 73.10(c) be reviewed as proposed, regardless of funding sources. This would eliminate the need for creation of an additional government entity and assure for appropriate pre-review and oversight of such experiments.

If the Proposed Interim Final Rule is finalized as written, we question whether the government should start proscribing experiments and if so, whether they should do it through federal

regulations? The proposed interim final rule does not specify who at HHS should review sensitive experiments.

2. 42 CFR 73.8: This provision sets forth the responsibility of the Department of Justice (DOJ) to process background checks on entities and individual researchers who possess, use, or transfer select agents.

> *(e) The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as a restricted person under paragraph (d)(1). The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as meeting the criteria of paragraph (d)(2) unless determined by the HHS Secretary to be warranted in the interest of the public health and safety or national security. For individuals meeting the criteria of paragraph (d)(2) the HHS Secretary may provide a limited approval for a specified time based upon the finding that circumstances warrant such action in the interest of the public health and safety or national security.*

We are disturbed that this provision does not fully establish nor provide details of an administrative appeals procedure for researchers to request review of their designation as a "restricted person".

In addition to the above concern, we strongly believe that the classification of Restricted Persons needs to be clarified. The proposed classifications are as follows:

> *(1) A restricted person under 18 U.S.C. 175b; or*
> *(2) Reasonably suspected by any Federal law enforcement or intelligence agency of:*
> *(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5);*
> *(ii) Having a knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or*
> *(iii) Being an agent of a foreign power (as defined in 50 USC 1801).*

We are concerned that these broad classifications will hinder legitimate research. For example, a dishonorable discharge from the U.S. military for homosexuality would preclude that person from ever working on select agents. We do not see how such an action will protect the security of the United States. Additionally, we request clarification on what "committed" (ever? involuntary? voluntary? self-committed?) and "mental institution" mean. These wide-ranging classifications will inevitably lead to confusion if not addressed at this time.

3. 42 CFR 73.11: This provision describes security plan components, establishing policy and procedures for the security of areas containing select agents and toxins.

> In 73.11 (a) it is stated that "*the security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.*"

We fully support a security system founded on risk-based analysis, similar to the risk-based approach presently used for biosafety in laboratory management and work with microbiological infectious organisms and described in Biosafety in Microbiological and Biomedical Laboratories (BMBL), written by the CDC and NIH. It has been demonstrated in laboratories throughout the United States and in much of the world that by the use of prudent practice, as depicted in the BMBL, safety for both workers and the public is maintained. We acknowledge that certain security factors must be addressed above and beyond practices presently in use in certain situations; however, we suggest that security requirements beyond those in current use correspond to the Biosafety level of the agent (e.g., vetting of all packages into and out of a laboratory need not be done for the lower level agents). We strongly believe that a "one size fits all" security system will not serve to the best advantage for researchers, the public, or the advancement of science. We request that the flexibility inherent in the existing BMBL approach to biosafety, a risk-based approach, be maintained in any security-related requirements.

Finally, an issue that is not presently addressed in the rule is the cost of compliance. HHS estimates cost of compliance to be $730,400 (for a medium university with a BSL2-3 lab). The Proposed Interim Final Rule's security requirements will increase operations and maintenance costs; these may be recovered by increases in the indirect cost recovery rate charged on federal grants. However, as these labs will also be used for other state-, private-, and institutionally-funded research, indirect rates most likely will not be adjusted for these new policies, thus making it unlikely that academic institutions will receive any increased indirect cost recovery. It is most likely that the majority of the related costs will not be recovered, and the proposed Interim Final Rule will create an unfunded mandate. Additionally, costs that are administrative may not be recovered at all due to the cap on administrative cost recovery. We request that mechanisms for the recovery of the cost of compliance be addressed.

Thank you for the opportunity to comment on this rule. If you have any questions, please do not hesitate to contact us.

Sincerely,

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